REMARKS

The May 31, 2007, Official Action and the references cited therein have been carefully reviewed. In view of the amendments presented herewith and the following remarks, favorable reconsideration and allowance of this application are respectfully requested.

At the outset, it is noted that a shortened statutory response period of three (3) months was set forth in the May 31, 2007, Official Action. Therefore, the initial due date for response is August 31, 2007. A petition for a three (3) month extension of time is presented with this response, which is being filed within the three month extension period.

At page 2 of the Official Action, the Examiner has rejected claims 93-100 under 35 U.S.C. §112, second paragraph for alleged indefiniteness.

Claims 91-93, 95-101 stand rejected under 35 U.S.C. § 112, first paragraph for allegedly failing to comply with the written description requirement of the statute.

The Examiner has rejected claims 91-100 under 35 U.S.C. §102(e) as allegedly anticipated by U.S. Patent No. 6,632,789.

Claims 91-93 and 96-101 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by Schultz et al.

Lastly, claims 91-94 and 96-100 have been rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,777,439. Applicants respectfully submits that the USPTO has already determined that the present claims are patentably distinct from those in the '439 patent. Indeed, in the restriction requirement issued in the US Patent Application 09/870,379, which issued as the '439

patent, the present examiner determined that claims directed to methods for inhibiting aberrant tumor angiogenesis were patentably distinct from claims directed to methods for preventing or inhibiting inflammatory disease in a patient. See Groups XVIII vs. XXV. Accordingly, the rejection for nonstatutory obviousness-type double patenting is improper in this case and should be withdrawn.

The foregoing objections and rejections constitute all of the grounds set forth in the May 31, 2007, Official Action for refusing the present application. Applicant respectfully requests reconsideration and examination of this application and the timely allowance of the pending claims in view of the amendments and arguments set forth below.

CLAIMS 94, 95, 97, 98 AND 101 AS AMENDED, SATISFY THE REQUIREMENTS OF 35 U.S.C. §112, SECOND PARAGRAPH

The Examiner has rejected claims 93-100 under 35 U.S.C. §112, second paragraph for alleged indefiniteness. The relevant inquiry in determining whether a given claim satisfies the requirements of 35 U.S.C. §112, second paragraph, is whether the claim sets out and circumscribes a particular area with a reasonable degree of precision and particularity such that the metes and bounds of the claimed invention are reasonably clear. In re Moore, 169 U.S.P.Q. 236 (CCPA 1971). Applicant respectfully submits that with respect to amended claims 94, 95, 97, 98 and 101 of the present application, such inquiry must be answered in the affirmative.

Regarding the rejection of claims 93-95, the Examiner contends that the phrase "further comprising the

administration of" is confusing. In response, Applicant has amended independent claim 91 to unambiguously describe the nature of the compound being administered, rendering this rejection moot. The Examiner has also rejected claims 96-100 since they allegedly do not further limit the independent claim. Applicant respectfully disagrees. However, to expedite the processing of the current application, Applicant has cancelled claims 96, 99 and 100 in response to the rejection, and added the recitation of inhibiting immunoreceptor signaling into claim 91. Claim 97 has been amended to omit the reference to ITAM bearing receptor, thereby obviating the rejection of this claim. It is respectfully submitted, that the dependent claims as amended clearly further limit the subject matter of claim 1.

In light of the foregoing remarks and claim amendments, Applicant respectfully requests that the above-mentioned rejections under 35 U.S.C. §112, second paragraph be withdrawn.

CLAIMS 91-92, 95 AND 101, AS AMENDED, SATISFY THE WRITTEN DESCRIPTION REQUIREMENT OF 35 U.S.C. §112, FIRST PARAGRAPH

Claims 91-93 and 95-101 stand rejected under 35 U.S.C. §112, first paragraph, as the specification allegedly fails to comply with the written description requirement. Specifically, the Examiner asserts that Applicant has not provided sufficient distinguishing characteristics of the genus of PTEN agonists, PI-3 kinase inhibitors, and AKT inhibitors since Applicant has only described the species LY294002 and Wortmannin, yet the genus includes a large number of unpredictable species.

Applicant respectfully disagrees with the Examiner's

position. In the sole interest of expediting prosecution of the instant application, Applicant has amended claim 91 to recite a Markush group consisting of LY294002 and Wortmannin. Dependent claim 95 has also been amended, and Applicant submits that the amended claims no longer read on the genus of PTEN agonists, PI-3 Kinase inhibitors or AKT inhibitors. Also, independent claim 91 has been amended to specify that the claimed method comprises "administering a PI-3 Kinase inhibitor" as opposed to a PTEN agonist. At page 5, first full paragraph of the Offical Action, the Examiner acknowledges that "LY294002 and Wortmannin, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph.

Thus, Applicant respectfully submits that the amendments to independent claims 91 to recite the specific species Applicant regards as the invention has rendered the written description rejection moot, and respectfully request its withdrawal.

CLAIMS 91-92 AND 94, 95, 97 AND 98 AS AMENDED, ARE NOT ANTICIPATED BY U.S. PATENT 6,632,789

The Examiner has rejected claims 91-100 under 35 U.S.C. §102(e) as allegedly anticipated by U.S. Patent 6,632,789 (the '789 patent) filed April 29, 1994, to Carl June. The '789 patent allegedly teaches a method of administering LY294002, and Wortmannin to inhibit a T-cell response.

Applicant respectfully submits that the '789 patent fails to disclose a method which is identical to that which is presently recited in amended claim 91. It is a well-settled premise in patent law that in order to constitute evidence of lack of novelty under 35 U.S.C. §102(b), a

prior art reference must identically disclose each and every element of the rejected claim. In re Bond, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990).

Applicant has amended claim 91 to recite a positive step of "assessing immunoreceptor signaling" following administration of the PI-3 kinase inhibitor. Support for this amendment can be found at page 4, lines 31-34, and in Example III on page 69, lines 29-31. Applicant submits that this amendment renders the §102 rejection over the '789 patent moot as this reference does not disclose such a step. Applicant has also amended claim 95 to remove the recitation of an AKT inhibitor, rendering the rejection based on Pendaries et al. moot.

CLAIMS 91-92 AND 101, AS AMENDED, ARE NOT ANTICIPATED BY SCHULTZ ET AL.

Claims 91-93 and 96-101 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by Schultz et al. (Anticancer Res. (1995) 15(4):1135-1139). Schultz et al. allegedly teach a method of administering Wortmannin orally to a patient, and it is the Examiner's position that since Applicant asserts that any PTEN agonist is able to prevent arthritis, the method of Schultz et al. inherently prevents arthritis.

As summarized in M.P.E.P. §2131, "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236 (Fed.

Cir. 1989).

Applicant respectfully submits that the Examiner has failed to make a proper showing of anticipation by Schultz et al. under §102(b) in the rejection of claims 91-93 and 96-101. On page 8 of the Official Action, the Examiner concludes that because Schultz et al. disclose the use of Wortmannin in Table VI, (note - Table VI does not exist, but Applicants believe the Examiner intended Table IV) for the treatment cancer, that the subject matter claimed by Applicant would have inherently been present. It appears that the Examiner believes that treatment of cancer with a PI-3 kinase inhibitor, like Wortmannin, as disclosed by Schultz et al., is treatment of an inflammatory disease.

Applicant respectfully submits that the Examiner's reliance on Schultz et al. as evidence is misplaced when viewed in light of MPEP at §2112 states that: "[i]n relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." Ex parte Levy, 17 USPQ2d 1461, 1464 (P.T.O. B.P.A.I. 1990)(emphasis in original).

Inherent anticipation requires inevitability. Therefore, to be inherent the result must be inevitable from the disclosure or the inherent characteristic must undeniably be present in the invention. Pingree v. Hull, 518 F.2d 624, 627 (C.C.P.A. 1975) (declaring "where support must be based on an inherent disclosure, it is not sufficient that a person following the disclosure might obtain the result … it must inevitably happen"). Even if Wortmannin is administered to a patient suffering from cancer, in such a patient, an inflammatory disease like

arthritis is not necessarily present. Cancer patients, which are the focus of Schultz et al., do not necessarily have arthritis. "The mere fact that a certain thing may result from a given set of circumstances is not sufficient." In re Robertson, 49 U.S.P.Q.2d 1949, 1950-51, (Fed. Cir. 1999). Whether a patient following Schultz et al. would have taken Wortmannin to inhibit inflammation is too speculative to be inherent. If a reference is ambiguous and can be interpreted so that it may or may not constitute an anticipation of appellant's claims, an anticipation rejection under 35 U.S.C. §102 is improper. See In re Brink, 164 U.S.P.Q. 247 (CCPA 1970). The Examiner may not rely on the concept of inherency to rewrite the disclosure of a prior art reference. Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1268 (Fed. Cir. 1991). Most importantly, Schultz et al. does not recite the newly added step of assessing immunoreceptor signaling following administration. For these reasons, Applicant submits that the Examiner's rejection based on Schultz et al. is improper and should be withdrawn.

CONCLUSION

In view of the amendments presented herewith and the foregoing remarks, it is respectfully urged that the objections and rejections set forth in the May 31, 2007, Official Action be withdrawn and that this application be passed to issue.

In the event the Examiner is not persuaded as to the allowability of any claim, and it appears that any

outstanding issues may be resolved through a telephone interview, the Examiner is requested to call the undersigned at the phone number given below.

Respectfully submitted,
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